

REMARKS

The status of the application is as follows.

Original Claims 1-23 were presented for prosecution.

Original Claims 9-23 were withdrawn from consideration as being non-elected, and are herein presently cancelled.

Claims 1-8 were previously amended and presently remain pending for consideration by the Examiner.

Claims 1, 5 and 7 are further amended herein.

Claims 3 and 6 are cancelled herein.

The Examiner noted that Applicant had previously listed claims 1-8, but non-compliantly (MPEP §714) omitted withdrawn claims 9-24 from that listing. In the interest of expediting prosecution, the Examiner graciously permitted the action to proceed on the merits. A full listing of claims 1-23, in compliance with MPEP §714, now appears in this Reply

The Examiner maintained her previous rejection of Claims 1-3, 5-7, in modified form under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for wild-type non-human mammals allegedly did not reasonably provide enablement for any existing transgenic, existing genetically-modified, or existing cloned animals.

The Examiner maintained her previous rejection of Claims 1-8, in modified form, under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record, March 14, 2005 and January 11, 2006. The Examiner noted that:

"'[S]ubstantially" is used to describe "permanent reduction" (claim 1, lines 8-9).

"Substantially" is a relative term and its metes and bounds are unclear." [Office Action mailed July 27, 2006: Page 7; Last line of 3rd Full Paragraph]

The Examiner maintained her rejections of Claims 1, 2, 4, 5, 7, 8 under 35 U.S.C. § 102(b) as being allegedly anticipated by Young et al., 1984, The American Journal of Clinical Nutrition, 40. 293·302 (hereinafter "Young, et al."), for reasons of record, 14 March 2005 and 11 January 2006.

Applicant respectfully replies to the Examiner's 35 U.S.C. § 112 first paragraph, 35 U.S.C. §112 second paragraph, and 35 U.S.C. §102(b) rejections, and requests reconsideration in light of the telephonic interview held on 31 August 2006, the amendments thereafter made herein and the accompanying remarks that follow. In view of the amendments herein, applicant respectfully submits that all of the pending claims are allowable over the prior art of record.

STATEMENT OF SUBSTANCE OF TELEPHONIC INTERVIEW MPEP §713.04

On 11 September 2006, the Examiner communicated an Interview Summary to applicant's attorney of record regarding a telephonic interview held on 31 August 2006. The Examiner's Interview Summary identified Young, et al., 1984 as prior art that was discussed in the course of the telephonic interview. With regard to the substance of the interview, the Interview Summary stated that:

"Issues regarding 102 and 112 1st were discussed. General guidance was provided as to how the 102 rejection could be approached to distinguish the instant invention from that of Young, et al. General guidance was also provided as to how to approach the 112, 1st

rejection. As indicated in the Office Action, it was suggested that Applicant provide representative examples (i.e. publications) of what animals are intended to be encompassed by the claimed invention.”

**REASONS PRESENTED AT INTERVIEW WARRANTING FAVORABLE ACTION
37 CFR §1.133 ¶(b)**

Applicant concurs with the foregoing statement of the Examiner, thanks the Examiner for her guidance and respectfully submits that leaving a residual *gastric pouch* that food enters and in which food is lodged while undergoing digestion was the reason presented by applicant’s attorney of record to the Examiner to patentably distinguish the instant invention from Young, et al., and to warrant favorable action with respect to the Examiner’s 102 rejection.

REMARKS RESPONSIVE TO 35 U.S.C. §112 FIRST PARAGRAPH REJECTION

The Examiner maintained her previous rejection of Claims 1-3, 5-7, in modified form under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for wild-type non-human mammals allegedly did not reasonably provide enablement for any existing transgenic, existing genetically-modified, or existing cloned animals. The Examiner noted that:

“The Zucker rat is not representative of the broad scope of all non-human transgenic, genetically modified, and cloned non-human mammals and thus does not enable an artisan to use the broad scope of any transgenic, genetically modified, and cloned non-human mammals. Should Applicant wish to claim more than the Zucker rat, teachings of the art indicating the existence of these non-human mammals should be provided.”

[Office Action mailed July 27, 2006: Page 4, 3rd Full Paragraph]

In response, the applicant has cancelled:

- Claim 3 directed to already existing *transgenic* nonhuman mammalian animals; and,
- claim 6 directed to already existing *cloned* mammalian nonhuman animals.

In further response, without adding any new matter, applicant has amended claim 5 and the specification to clearly limit the use of genetically modified mammalian nonhuman animals already in existence *that express an obese phenotype* at the time that they are selected for the surgical modification productive of the animal model claimed herein. Inasmuch as the Zucker rat represents an existing, indeed longstanding, genetic modification (mutation) of a wild type rat that expresses an obese phenotype, the Zucker rat is, as suggested by the Examiner, representative only of those existing genetically modified nonhuman mammals that express an obese phenotype. The specification herein has accordingly been amended to include exemplary teachings of the art indicating the existence of other genetically modified nonhuman mammalian animals that express an obese phenotype, as required by the Examiner. [Office Action mailed July 27, 2006: Page 4; 3rd Full Paragraph]

REMARKS RESPONSIVE TO 35 U.S.C. § 112 SECOND PARAGRAPH REJECTION

The Examiner rejected Claims 1-8 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, as regards the use of the word "substantially" as a modifier of the words "permanent reduction." [Office Action mailed July 27, 2006: Page 5; 4th Full Paragraph]

In response, the applicant has deleted the adjective "substantially" as a modifier of the words "permanent reduction" everywhere that the adjective "substantially" modified the words "permanent reduction" throughout the Original Specification and in Claim 1. Applicant respectfully refers the Examiner to Page 14, Lines 9-16 of the Specification, wherein it is stated, ***without*** the use of modifier "substantially," that:

"[T]he Roux-en-Y gastroplasty is an example of a surgical modification of the gastrointestinal tract that may be used: ...
[iii] to effect a permanent reduction in the animal's gastric output of ghrelin; and,
[iv] to effect a permanent reduction in the animal's weight relative to its pre-surgical weight." [emphasis provided]

Accordingly, no new matter has been added by the deletion of the modifier "substantially" from the specification and Claim 1.

REMARKS RESPONSIVE TO 35 U.S.C. §102(b) REJECTIONS

The Examiner maintained her rejection of Claims 1, 2, 4, 5, 7, 8 under 35 U.S.C. §102(b) as being allegedly anticipated by Young et al., 1984, *The American Journal of Clinical Nutrition*, 40. 293:302 (hereinafter “Young, et al.”), under the doctrine of inherency. The applicant gratefully acknowledges the guidance of the Examiner given during a telephone conference held on 31 August 2006, in which the applicant explained that the surgeries encompassed by Claim 8 to create the nonhuman mammalian animal model encompassed by Claim 1, in all cases left a patently distinct *residual gastric pouch* that food enters and in which food is lodged while undergoing digestion, the existence or presence of which was neither expressly nor inherently taught in Young, et al.

Applicant has accordingly amended the Original Specification and Claims to limit the claimed surgical modification to a nonhuman mammalian animal in which the claimed surgical modification reduces the volume of a functional stomach, leaving a residual gastric pouch that food enters and in which food is lodged while undergoing digestion.

REQUEST FOR EXTENSION OF TIME

The Applicant herewith petitions the Commissioner of Patents and Trademarks to charge Deposit Account No. 503033 if any additional fees, including additional extension of time fees, are due as a result of this response.

This submission of a fee and authorization to charge Deposit Account No. 503033 is intended to act as a constructive petition for an additional extension of time, should an additional

Serial No. 10/802,996

extension of time be needed as a result of this Response. Please credit any overpayment to the above referenced deposit account.

CONCLUSION

In summary, as presently amended and based on the preceding remarks, Applicant respectfully believes that independent claim 1 and all claims dependent therefrom meet the acceptance criteria for allowance and therefore, upon the Examiner's reconsideration, requests allowance.

The Examiner is invited to telephone the undersigned if this would in any way advance the prosecution of this case. If the Examiner believes that anything further would in any way advance the prosecution of this case or be helpful to place the application in condition for allowance, the Examiner is invited to contact applicant's attorney at the telephone number listed below.

Respectfully submitted,

/Sander Rabin/

Sander Rabin, MD JD October 24, 2006

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Serial No. 10/802,996